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09/647,098	05/02/2001	David Grant Richards		3884

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EXAMINER
FORD, VANESSA L

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/647,098	Applicant(s)	
	Examiner Vanessa L. Ford	Art Unit 1645	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL ACTION

1. This Office Action is responsive to Applicant's amendment and response and filed December 19, 2002. Claims 1-10 have been amended. Appendices A and B are acknowledged.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Objections/Rejections Withdrawn

3. In view of Applicant's amendment and response, the following objections and rejections are withdrawn:

a) Objection to claim 2, page 2 paragraph 2 of the previous Office action.
b) Rejection of claims 1-10 under 35 U.S.C. 112 first paragraph, pages 2-6, paragraph 3 of the previous Office action.
c) Rejection of claim 2 under 35 U.S.C. 112, second paragraph, page 8, paragraph 5 of the previous Office action.
d) Rejection of claim 8 under 35 U.S.C. 112, second paragraph, page 8, paragraph 6 of the previous Office action.
e) Rejection of claims 1-10 under 35 U.S.C. 112, second paragraph, page 8, paragraph 7 of the previous Office action.

Rejections Maintained

4. The rejection of claims 1-10 under 35 U.S.C. 112, first paragraph is maintained for the reasons set forth on pages 6-7, paragraph 4 of the previous Office Action.

The rejection was on the grounds that claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the

specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Claims 1-10 are drawn to a vaccine which includes one or more strains of *Eimeria* of *E. maxima* ARI-73/97, *E. acervulina* ARI-77/97, *E. tenella* ARI-11/98, *E. necatrix* MCK01 and/or *E. necatrix* ARI-MEDNEC$_3$+8 or antigens of said one or more strains in association with a veterinarially acceptable carrier or excipient.

Despite the knowledge in the art for attenuating strains for use in coccidiosis vaccines, the specification fails to provide guidance regarding whether the *Eimeria strains* used in the claimed invention are cross-reactive since combined vaccines are encompassed by the claimed invention. The specification discloses in Example 2 that a series of trials was carried out using the vaccines containing each of the strains produced in Example 1, combinations of 2 to 4 of these strains as well as combinations of strains according to Example 1 combined with other vaccine strains to give a vaccine (page 8). What are the other strains used in the claimed vaccine? The specification states that in "one experiment sporocysts of *E. maxima* ARI-73/97, *E. acervulina* ARI-77/97 were combined in a vaccine with Medichick strain *E. necatrix* and the Darryl strain *E. tenella* and birds were vaccinated with a vaccine containing 250 sporulated oocysts of each strain in 1 ml of saline." What antigens were isolated and used in the claimed vaccines? The specification states "all these vaccines showed excellent protection against infection with heterologous *Eimeria* strains as well as treatment of *Eimeria* infection" (page 8). Where are the data that correspond to the specification's assertion that all of the vaccines of the claimed invention were protective?

The specification fails to provide guidance regarding how to make and use the claimed invention. Protocols and procedures such as isolation of antigen, identification of other strains used in the series of trials and data obtained when animals were vaccinated/challenged with each of the claimed vaccines are not specifically provided in the Applicant's specification. The metes and bounds of the claimed invention cannot be ascertained by the information disclosed in the specification. Therefore, one of skill in the art would require guidance, in order to make or use the claimed invention in a manner reasonable in correlation with the scope of the claims. Without proper guidance, the experimentation is undue.

Applicant urges that the claimed vaccine is fully enabled with respect to the specifically recited *Eimeria* strains included. Applicant urges that the specification teaches how to isolate the *Eimeria* strains claimed and how to produce an effective vaccine using these strains. Applicant urges that the specific strains have been deposited under the terms of 37 C.F.R. 1.801-1.809. Applicant urges that Example 2 of the specification teaches various combinations of 2 to 4 of the specifically recited *Eimeria* strains along with other strains were made and shown to give excellent protect against infections with heterologous *Eimeria* strains. Applicant urges that using this information together with common knowledge a person skilled in the art could readily produce a vaccine using any one or more of the novel *Eimeria* strains and determine whether it is effective against disease. Applicant refers to Appendix A, an interim study on the effectiveness of a four species live coccidiosis vaccine comprising four strains directly derived from the strains deposited in relation to the present invention. Applicant urges that the data presented in this study shows that a protective effect is achieved with each strain present and the individual strains do not have any adverse effect on each other in terms of immunity. Applicant refers to Appendix B (Williams et al, 1997) to support the position that all *Eimeria* species in a vaccine provide protective immunity when administered concurrently.

Applicant's arguments filed December 19, 2002 have been fully considered but they are not persuasive. It is the Examiner's position that the specification fails to teach how to make and use the claimed invention. Applicant has failed to disclose which *Eimeria* strains are used in the combination vaccines disclosed in Example 2 of

the specification. It cannot be determined by the information disclosed in the interim study as to which specific species of *Eimeria* strains are used in the combination vaccines. Are all of the deposited strains used? What constitutes "*Eimeria* strain A, *Eimeria* strain B, *Eimeria* strain C or *Eimeria* strain D? The interim study discloses that all chickens were challenged at 30 days of age with a "x80 dose of the vaccine". What constitutes the "x80 dose vaccine"? The Examiner agrees with Williams regarding all 7 species of *Eimeria* have been shown to stimulate immunity. However, in the instant case, Applicant has not disclosed which species of *Eimeria* are contained in the claimed vaccine nor has Applicant made a correlation between the deposited *Eimeria* species, the *Eimeria* species used in the combination vaccines disclosed in the specification (example 2) and the *Eimeria* species used in the combination vaccines of the Applicant's interim study. The isolation and testing of antigens are limitations of the claimed invention. Protocols and procedures for isolation of antigen, testing the antigens that were isolated and the identification of all strains used in the series of trials are not specifically provided in the Applicant's specification or interim study. Without guidance, the skilled artisan cannot make the determination that all deposited strains that may be used in Applicant's claimed vaccine are protective. Therefore, one of skill in the art would require guidance, in order to make or use the claimed invention in a manner reasonable in correlation with the scope of the claims. Without proper guidance, the experimentation is undue.

5. The rejection of claims 1-4 and 7-10 as anticipated by or as being obvious over McDonald et al is maintained for the reasons set forth on page 9-10, paragraph 8 of the previous Office Action.

The rejection was on the grounds that McDonald et al teach vaccines against coccidiosis in domestic fowls that contain attenuated precocious strains of *Eimeria* species (see the Abstract). McDonald et al teach a vaccine that contains *E. aceruvlina*, *E. maxima*, *E. tenella*, *E. necatrix*, *E. mitis*, *E. brunetti* and *E. praecox* (claim 1, column 14). McDonald et al teach that the vaccines of their invention include chicken feed or drinking water containing the attenuated *Eimeria* strains (column 6).

McDonald et al do not specifically teach one or more strains of *E. maxima* ARI-73/97, *E. acerculina* ARI-77/97, *E. tenella* ARI-11/98, E. necatrix MCK01 and/or *E. necatrix* ARI-MEDNEC$_3$+8 or antigens of said strains. However, in the alternative the strains of McDonald, et al appear to be obvious or analogous variants of the claimed vaccine strains. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the bacteria strains of McDonald et al in a vaccine against coccidiosis because McDonald teach vaccines active against coccidiosis in domestic fowls that contain attenuated precocious strains of *Eimeria* species. It would have been expected, barring evidence to the contrary, that vaccines comprising multiple *Eimeria* species as taught by McDonald et al would be effective in the prevention and control of coccidiosis in poultry.

Applicant urges that McDonald et al do not teach or suggest each element of the rejected claims and therefore does not anticipate or make obvious the claimed invention. Applicant urges that the claims have been amended to recited a vaccine that comprises one or more of the five attenuated *Eimeria* strains prepared by the Applicants. Applicant urges that the vaccines of the present invention must contain at least one of the novel *Eimeria* strains prepared by the Applicants and McDonald et al do not teach or suggest any of the five novel strains recited in the claims of the present application. Applicant urges that they prepared a number of different attenuated strains of each species of *Eimeria* used in the present invention by serial passage and by selecting for rapid development. Applicant urges that it is clear the different isolates of

each species were distinct strains with distinct characteristics and the skilled artisan would not expect that the different attenuated isolates of *Eimeria* recited in claim to be the same as the *Eimeria* strains of McDonald et al.

Applicant's arguments filed December 19, 2002 have been fully considered but they are not persuasive. Applicant has provided no side-by-side comparison to show: that the *Eimeria* strains of the prior art reference are not the same as the claimed *Eimeria* strains since they both have the same or similar characteristics. Applicant is arguing limitations that are not in the claims with the assertion that "that they prepared a number of different attenuated strains of each species of *Eimeria* used in the present invention by serial passage and by selecting for rapid development". There is no requirement or limitation in the claims regarding passaging or selecting for rapid development. However, McDonald et al teach that attenuated *Eimeria* strains are prepared by serial passage (column 2, lines 31-43). Therefore, there is nothing on the record to show why the vaccine comprising *Eimeria* strains of the reference is not the same as the claimed vaccine comprising *Eimeria* strains.

6. The rejection of claims 1-10 as anticipated by or as being obvious over Shirley is maintained for the reasons set forth on pages 10-11, paragraph 9 of the previous Office Action.

The rejection was on the grounds that Shirley teaches a vaccine composition which comprises live attenuated strains of *Eimeria* species in particular *E. necatrix* and *E. acervulina*. Shirley teaches that the *Eimeria* species may be in the form of sporocysts and that other *Eimeria* species such as *E. maxima*, *E. brunetti*, *E. mivati*, *E. tenella* and *E. praecox* may be added to provide a fully effective coccidiosis vaccine (column 4, lines 35-41). Shirley teaches that other vaccines comprising antigenic

material from other species of organisms besides *Eimeria* may be used in the invention (column 4, lines 54-56). Shirley teaches that the vaccines are formulated using a sterile aqueous medium which may contain suspension agents such as gelatin (column 4, lines 60-63).

Shirley does not specifically teach one or more strains of *E. maxima* ARI-73/97, *E. acerculina* ARI-77/97, *E. tenella* ARI-11/98, E. necatrix MCK01 and/or *E. necatrix* ARI-MEDNEC$_3$+8 or antigens of said strains. However, in the alternative, the strains of Shirley appear to be obvious or analogous variants of the claimed vaccine strains. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the bacteria strains of Shirley in a vaccine against coccidiosis because Shirley teaches that live vaccines comprising attenuated strains of *Eimeria* species may be formulated in the feed or drinking water of animals and these vaccines are used to prevent and control coccidiosis in poultry. It would have been expected, barring evidence to the contrary, that vaccines comprising multiple *Eimeria* species as taught by Shirley would be effective in the prevention and control of coccidiosis in poultry.

Applicant urges that claim 1 of the present invention recites a vaccine that comprises one or more of the five attenuated *Eimeria* strains prepared by the Applicants. Applicant urges that the vaccines of the present invention must contain at least one of the novel *Eimeria* strains prepared by the Applicants. Applicant urges that there is no evidence that the strains disclosed in Shirley are the same as those of the present invention nor would the skilled artisan expect that they are the same. Applicant urges that Shirley does not teach or suggest any of the five novel strains recited in claim 1 of the present application and Shirley does not anticipate or make obvious the claimed invention.

Applicant's arguments filed December 19, 2002 have been fully considered but they are not persuasive. Applicant has provided no side-by-side comparison to show: that the *Eimeria* strains of the prior art reference are not the same as the claimed *Eimeria* strains since they both have the same or similar characteristics. There is

nothing on the record to show why the vaccine comprising *Eimeria* strains of the reference is not the same as the claimed vaccine comprising *Eimeria* strains.

7. The rejection of claims 1-10 as anticipated by or as being obvious over Schmatz is maintained for the reasons set forth on pages 12-13, paragraph 10 of the previous Office Action.

The rejection is on the grounds that Schmatz et al teach live sporulated oocysts that are administered to one day old chickens to provide immunity against coccidiosis without the need to provide supplemental anticoccidial therapy (see the Abstract). Schmatz et al teach that the vaccines of their invention include *E. necatix, E. acervulina, E, brunetti, E. mitis, E. mivati, E. praecox* and *E. tenella* (page 2). Schmatz et al teach that the dosages of attenuated precocious oocysts range from about 5 to 1000 oocysts per bird for each *Eimeria* species included in the vaccine (page 3). Schmatz et al teach that the vaccines of their invention are preferably administered along with other material when the chicks are first processed. Process which administers other material to the chick, such as other vaccines. Schmatz et al teach that the aqueous oral suspensions of their invention include one or more suspending agents, thickeners or preservatives (claim 7, page 10).

Schmatz et al do not specifically teach one or more strains of *E. maxima* ARI-73/97, *E. acerculina* ARI-77/97, *E. tenella* ARI-11/98, E. necatrix MCK01 and/or *E. necatrix* ARI-MEDNEC$_3$+8 or antigens of said strains. However, in the alternative, the strains of Schmatz, et al appear to be obvious or analogous variants of the claimed vaccine strains. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the bacteria strains of Schmatz et al in a vaccine against coccidiosis because Schmatz et al teach vaccines that comprise live, attenuated, precocious strains of coccidial species, in particular *Eimeria.* It would have been expected, barring evidence to the contrary, that vaccines comprising multiple *Eimeria* species as taught by Schmatz et al would be effective in the prevention and control of coccidiosis in poultry.

Applicant urges that claim 1 of the present invention recites a vaccine that comprises one or more of the five attenuated *Eimeria* strains prepared by the Applicants. Applicant urges that the vaccines of the present invention must contain at least one of the novel *Eimeria* strains prepared by the Applicants. Applicant urges that

there is no evidence that the strains disclosed in Schmatz et al are the same as those of the present invention nor would the skilled artisan expect that they are the same. Applicant urges that Schmatz et al does not teach or suggest any of the five novel strains recited in claim 1 of the present application and Schmatz et al does not anticipate or make obvious the claimed invention.

Applicant's arguments filed December 19, 2002 have been fully considered but they are not persuasive. Applicant has provided no side-by-side comparison to show: that the *Eimeria* strains of the prior art reference are not the same as the claimed *Eimeria* strains since they both have the same or similar characteristics. There is nothing on the record to show why the vaccine comprising *Eimeria* strains of the reference is not the same as the claimed vaccine comprising *Eimeria* strains.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
April 3, 2003

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